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# TRANSMITTAL FORM

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| | | Filing Date | July 9, 2001 |
| | | First Named Inventor | J. J. SEILHAMER |
| | | Art Unit | 1635 |
| | | Examiner Name | J. Epps Ford |
| Total Number of Pages in This Submission | 70 | Attorney Docket Number | 219002025213 |

## ENCLOSURES (*Check all that apply*)

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|---|---|---|
| [X] Fee Transmittal Form (1 page + duplicate) | [ ] Drawing(s) | [ ] After Allowance communication to Technology Center (TC) |
| [ ] Fee Attached | [ ] Licensing-related Papers | [ ] Appeal Communication to Board of Appeals and Interferences |
| [X] Amendment/Reply (7 pages) | [ ] Petition | [ ] Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)** |
| [ ] After Final | [ ] Petition to Convert to a Provisional Application | [ ] Proprietary Information |
| [ ] Affidavits/declaration(s) | [ ] Power of Attorney, Revocation Change of Correspondence Address | [ ] Status Letter |
| [X] Extension of Time Request (1 page) | [ ] Terminal Disclaimer | [X] Other Enclosure(s) (please Identify below): Copy of U.S. Patent 6,613,886 (53 pages)<br>Copy of Discussion on Antibodies (6 pages)<br>Return Receipt Postcard |
| [ ] Express Abandonment Request | [ ] Request for Refund | |
| [ ] Information Disclosure Statement | [ ] CD, Number of CD(s) _____ | |
| [ ] Certified Copy of Priority Document(s) | | |
| [ ] Response to Missing Parts/ Incomplete Application | Remarks | |
| [ ] Response to Missing Parts under 37 CFR 1.52 or 1.53 | CUSTOMER NO. 25225 | |

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

| | |
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| Signature | Kate H. Murashige |
| Date | July 28, 2004 |

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: July 29, 2004 Signature: Rebecca (Rebecca McElroy)

sd-211605

**Example 16: <u>Antibodies</u>**

**Specification:** The specification teaches that antigen X has been isolated and is useful for detection of HIV infections. The specification teaches antigen X as purified by gel filtration and provides characterization of the antigen as having a molecular weight of 55 KD. The specification also provides a clear protocol by which antigen X was isolated. The specification contemplates but does not teach in an example antibodies which specifically bind to antigen X and asserts that these antibodies can be used in immunoassays to detect HIV. The general knowledge in the art is such that antibodies are structurally well characterized. It is well known that all mammals produce antibodies and they exist in five isotypes, IgM, IgG, IgD, IgA and IgE. Antibodies contain an effector portion which is the constant region and a variable region that contains the antigen binding sites in the form of complementarity determining regions and the framework regions. The sequences of constant regions as well as the variable regions subgroups (framework regions) from a variety of species are known and published in the art. It is also well known that antibodies can be made against virtually any protein.

**Claim:** An isolated antibody capable of binding to antigen X.

**Analysis:**

A review of the full content of the specification indicates that antibodies which bind to antigen X are essential to the operation of the claimed invention. The level of skill and knowledge in the art of antibodies at the time of filing was such that production of antibodies against a well-

characterized antigen was conventional. This is a mature technology where the level of skill is high and advanced.

The claim is directed to any antibody which is capable of binding to antigen X.

A search of the prior art indicates that antigen X is novel and unobvious.

Considering the routine art-recognized method of making antibodies to fully characterized antigens, the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature, one of skill in the art would have recognized that the spectrum of antibodies which bind to antigen X were implicitly disclosed as a result of the isolation of antigen X.

**Conclusion:** The disclosure meets the requirement under 35 USC 112 first paragraph as providing an adequate written description of the claimed invention.

**Example 16: <u>Antibodies</u>**

**Specification:** The specification teaches that antigen X has been isolated and is useful for detection of HIV infections. The specification teaches antigen X as purified by gel filtration and provides characterization of the antigen as having a molecular weight of 55 KD. The specification also provides a clear protocol by which antigen X was isolated. The specification contemplates but does not teach in an example antibodies which specifically bind to antigen X and asserts that these antibodies can be used in immunoassays to detect HIV. The general knowledge in the art is such that antibodies are structurally well characterized. It is well known that all mammals produce antibodies and they exist in five isotypes, IgM, IgG, IgD, IgA and IgE. Antibodies contain an effector portion which is the constant region and a variable region that contains the antigen binding sites in the form of complementarity determining regions and the framework regions. The sequences of constant regions as well as the variable regions subgroups (framework regions) from a variety of species are known and published in the art. It is also well known that antibodies can be made against virtually any protein.

**Claim:** An isolated antibody capable of binding to antigen X.

**Analysis:**

A review of the full content of the specification indicates that antibodies which bind to antigen X are essential to the operation of the claimed invention. The level of skill and knowledge in the art of antibodies at the time of filing was such that production of antibodies against a well-

characterized antigen was conventional. This is a mature technology where the level of skill is high and advanced.

The claim is directed to any antibody which is capable of binding to antigen X.

A search of the prior art indicates that antigen X is novel and unobvious.

Considering the routine art-recognized method of making antibodies to fully characterized antigens, the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature, one of skill in the art would have recognized that the spectrum of antibodies which bind to antigen X were implicitly disclosed as a result of the isolation of antigen X.

**Conclusion:** The disclosure meets the requirement under 35 USC 112 first paragraph as providing an adequate written description of the claimed invention.

**Example 16: <u>Antibodies</u>**

**Specification:** The specification teaches that antigen X has been isolated and is useful for detection of HIV infections. The specification teaches antigen X as purified by gel filtration and provides characterization of the antigen as having a molecular weight of 55 KD. The specification also provides a clear protocol by which antigen X was isolated. The specification contemplates but does not teach in an example antibodies which specifically bind to antigen X and asserts that these antibodies can be used in immunoassays to detect HIV. The general knowledge in the art is such that antibodies are structurally well characterized. It is well known that all mammals produce antibodies and they exist in five isotypes, IgM, IgG, IgD, IgA and IgE. Antibodies contain an effector portion which is the constant region and a variable region that contains the antigen binding sites in the form of complementarity determining regions and the framework regions. The sequences of constant regions as well as the variable regions subgroups (framework regions) from a variety of species are known and published in the art. It is also well known that antibodies can be made against virtually any protein.

**Claim:** An isolated antibody capable of binding to antigen X.

**Analysis:**

A review of the full content of the specification indicates that antibodies which bind to antigen X are essential to the operation of the claimed invention. The level of skill and knowledge in the art of antibodies at the time of filing was such that production of antibodies against a well-

characterized antigen was conventional. This is a mature technology where the level of skill is high and advanced.

The claim is directed to any antibody which is capable of binding to antigen X.

A search of the prior art indicates that antigen X is novel and unobvious.

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**Conclusion:** The disclosure meets the requirement under 35 USC 112 first paragraph as providing an adequate written description of the claimed invention.